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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,441	05/10/2000	LASZLO BALAZS	1060-136P	1924
2292	7590	03/18/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/485,441

Applicant(s)

BALAZS ET AL.

Examiner

Brenda L. Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,9 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,9 and 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Claims 1, 9 and 16-19 are pending in the application.

This action is in response to applicant's amendments dated November 25, 2003.

Claims 1, 9 and 16-19 have been amended.

### ***Response to Arguments***

Applicant's arguments filed November 25, 2003 have been fully considered with the following effect:

1. The applicant's amendments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 1, 9, 16, 17 and 19 of the last office action which is hereby **withdrawn**.
2. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejection labeled paragraph 3b) and 3u) of the last office action which are hereby **withdrawn**.
3. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejection labeled paragraph 5 of the last office action which are hereby **withdrawn**.

In view of the amendment dated November 25, 2003, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 16, 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

- a) Claim 16 is vague and indefinite in that it is not known what is meant by the proviso at the end of the claim where "one of  $R^2$  and  $R^3$  is hydrogen and the other is  $C_{1-4}$  alkyl optionally substituted with a 5 to 6 membered saturated heterocyclic ring".  $R^3$  can at no time be hydrogen.
- b) Claim 17 is vague and indefinite in that it is not known what is meant by the proviso at the end of the claim where "**one of**  $R^2$  is hydrogen and  $R^3$  is  $C_{1-4}$  alkyl optionally substituted with a 5 to 6 membered saturated heterocyclic ring".
- c) Claim 19 recites the limitation "0" in the definition of n in the process labeled
- (d). There is insufficient antecedent basis for this limitation in the claim.
- d) Claim 19 is vague and indefinite in that it is not known what is meant by the process of a-e, since there is no process e in claim 19.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(f) he did not himself invent the subject matter sought to be patented.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

**NOTE:** The following 102(b) rejections were withdrawn upon the applicant's amendment to formula (I) where the double bond between the 5 and 6 position of the 9H-1,3-dioxolo[4,5-h][2,3]benzodiazepine ring was removed. However, in view of the amendment to formula I replacing the double bond between the 5 and 6 position of the 9H-1,3-dioxolo[4,5-h][2,3]benzodiazepine ring the following rejections are reinstated.

5. Claims 1, 9, 16, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamori et al., WO 96/04283. Hamori teaches the compounds, compositions and method of use of the instant invention where instant X and Y form a bond; R is -NHMe; and R<sup>1</sup> of WO 96/04283 is 4-amino. See examples 45.

6. Claims 1, 9, 16, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Tarnawa et al., Bioorganic & Medicinal Chemistry Letters. Tarnawa teaches the compounds, compositions and method of use of the instant invention where instant X and Y are hydrogen; R is -NHMe, -NHC<sub>4</sub>H<sub>9</sub>, -CH<sub>2</sub>NHCH<sub>3</sub>. See examples 15, 16 and 19.

7. Claims 1, 9 and 16-19 are rejected under 35 U.S.C. 102(b, f and g) as being anticipated by Andrási et al., U.S. Patent Numbers 5,639,751; 5,459,137; 5,521,174;

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5,519,019; 5,604,223; and 5,536,832. Andrási teaches the compounds, compositions and method of use of the instant invention where X and Y are both hydrogen; R is -NHMe, -CH<sub>2</sub>-NMe<sub>2</sub>, -NHn-Bu, -CH<sub>2</sub>-NHMe, etc. See examples 98, 100, 114, 116, etc.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 9 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamori et al., WO 96/04283. The generic structure of Hamori encompasses the instantly claimed compounds (see Formula I, page 1) and by the same process (see page 7) as claimed herein. Example 45 differ only in the nature of the R<sup>1</sup> and R<sup>3</sup> substituents. Page 3, defines the substituent R<sup>1</sup> as .....the group -NR<sup>8</sup>R<sup>9</sup>, ..... and R<sup>3</sup> as the group -C(=O)-R<sup>10</sup>. Page 2, defines the substituents R<sup>8</sup> and R<sup>9</sup> as hydrogen and R<sup>10</sup> is defined as ...optionally substituted C<sub>1</sub>-C<sub>6</sub> alkyl.... the group -NR<sup>11</sup>R<sup>12</sup>, wherein R<sup>11</sup> and R<sup>12</sup> are hydrogen, optionally substituted C<sub>1</sub>-C<sub>6</sub> alkyl or optionally substituted aryl. Compounds of the instant invention are generically embraced by Hamori in view of the interchange ability of the R<sup>1</sup> and R<sup>3</sup> substituents of the tricyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example chloromethyl for instant R as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

9. Claims 1, 9 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over András et al., U.S. Patent Numbers 5,639,751; 5,459,137; 5,521,174; 5,519,019; 5,604,223; and 5,536,832. The generic structure of András et al. encompasses the instantly claimed compounds (see Formula I) and by the same process as claimed herein.

Examples 98, 100, 114, 116, etc. differ only in the nature of the R, R<sup>3</sup> and R<sup>4</sup> substituents. Column 1, defines the substituent R as a C<sub>1-6</sub> alkanoyl group optionally substituted by a methoxy, cyano, carboxyl, amino, C<sub>1-4</sub> alkylamino, di(C<sub>1-4</sub> alkyl)amino, pyrrolidino, phthalimido or phenyl group, or by one or more halogen(s); or R is benzoyl, cyclopropanecarbonyl, C<sub>1-5</sub> alkylcarbamoyl or phenylcarbamoyl; R<sup>3</sup> is hydrogen or a C<sub>1-4</sub> alkanoyl; and R<sup>4</sup> is hydrogen; a C<sub>1-6</sub> alkanoyl group optionally substituted by a methoxy, cyano, carboxyl, amino..... Compounds of the instant invention are generically embraced by András et al. in view of the interchange ability of the R, R<sup>3</sup> and R<sup>4</sup> substituents of the tricyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example chloroethyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

### **Conclusion**

10. Applicants' attention is directed to U.S. Patent Numbers 5,639,751 (claims 1 and 3); 5,521,174 (claims 1 and 3); 5,519,019 (claims 1 and 3); 5,604,223 (claims 1 and 3); 5,459,137 (claims 1, 5 and 6) and 5,536,832 (claims 1, 5 and 6), claims subject matter that is similar and/or identical to that claimed herein. Two patents cannot issue on the same subject matter, unless applicants can demonstrate that the claims are patentably distinct

from the claims of this US patent, the only way to overcome this patent is by way of Interference proceedings or removal of the conflicting subject matter. See MPEP 2306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman  
Primary Examiner Art Unit 1624  
March 15, 2004